These notes refer to the Health and Social Care (Safety and Quality) Bill as introduced in the House of Commons on 2 July 2014 [Bill 17]

HEALTH AND SOCIAL CARE (SAFETY AND QUALITY) BILL

EXPLANATORY NOTES

INTRODUCTION

1. These Explanatory Notes relate to the Health and Social Care (Safety and Quality) Bill as introduced in the House of Commons on 2nd July 2014. The Notes have been prepared by the Department of Health, with the consent of Jeremy Lefroy, the Member in charge of the Bill, in order to assist the reader of the Bill and to help inform debate in the House of Commons. They do not form part of the Bill and have not been endorsed by Parliament.

2. These Notes need to be read in conjunction with the text of the Bill. They are not, and are not meant to be, a comprehensive description of the Bill. So where a clause or part of a clause does not seem to require any explanation or comment, none is given.

SUMMARY

3. The Health and Social Care (Safety and Quality) Bill contains measures that together are intended to improve the safety and quality of health services and social care. Specifically it:

   a) seeks to ensure that certain health and social care-related services in England cause their users no avoidable harm;
   b) makes provision for requiring the use of a consistent service user identifier in individuals' health and social care records in England;
   c) is intended to secure the appropriate sharing of information in support of people's direct care in England to help ensure more integrated care;
   d) seeks to give the Professional Standards Authority for Health and Social Care ('PSA') and certain regulators of health and social care

professionals in the United Kingdom an overarching objective of public protection. It also requires those regulators' committees and panels to have regard to the new objective when determining whether a practitioner is fit to practise and when determining what sanctions might be appropriate. The overarching objective involves the pursuit of objectives in relation to maintaining public safety, public confidence and proper standards and conduct.

TERRITORIAL EXTENT AND APPLICATION

4. Clause 6 sets out the territorial extent of the Bill. The territorial extent is mixed. Clauses 1 to 4 extend to England and Wales but apply to England only. Clauses 5 and 6 of the Bill and paragraphs 1 to 6 of the Schedule extend to the whole of the United Kingdom. The provision in Paragraph 7 of the Schedule, in relation to the objectives of the General Pharmaceutical Council ('GPhC'), extends to Great Britain only. This reflects the jurisdiction of the GPhC.

5. The Bill contains provisions that trigger the Sewel Convention. The provisions relate to the regulation of health professionals, which is a devolved matter in Scotland in relation to those health professions brought into regulation since devolution. The Sewel Convention provides that Westminster will not normally legislate with regard to devolved matters without the consent of the Scottish Parliament. The consent of the Scottish Parliament is therefore being sought for these provisions through a legislative consent motion. If there are amendments relating to such matters which trigger the Convention, the consent of the Scottish Parliament will be sought for them.

6. Similarly, the regulation of health professionals is a devolved matter in Northern Ireland. As there are provisions in this Bill relating to such matters, the consent of the Northern Ireland Assembly is being sought through a legislative consent motion.

COMMENTARY ON CLAUSES

Clause 1 – Harm-free care

7. This clause amends section 20 of the Health and Social Care Act 2008 (regulation of regulated activities). It provides that the Secretary of State must make regulations imposing requirements on health and social care service providers required to register

with the Care Quality Commission ('CQC') to help secure that health and adult social care services in England are provided in a way that causes no avoidable harm.

8. The amendment has the effect of removing the Secretary of State's discretion around whether the requirements for registration with CQC should cover safety of care. This duty will not require the Secretary of State to secure that care or treatment is risk free, but that requirements are imposed to secure that services are provided in a safe way. Also, a test of reasonableness applies in assessing whether or not harm is avoidable, to acknowledge the risk intrinsic in many clinical treatments.

Clause 2 – Consistent identifiers

9. This clause amends Part 9 of the Health and Social Care Act 2012 ('HSCA 2012') which enables the Secretary of State or the NHS Commissioning Board to set information standards for health and adult social care services in England; and which establishes the Health and Social Care Information Centre. This clause inserts new section 251A (consistent identifiers) into Part 9 of the HSCA 2012.

10. Subsection (1) of section 251A imposes a duty on the Secretary of State to make regulations specifying a description of consistent identifier.

11. Subsection (2) defines a consistent identifier as any identifier such as, for example, a number or code used for identification purposes, that relates to an individual and forms part of a set of similar identifiers that is of general application. An example of a consistent identifier that meets these criteria which the Secretary of State may specify in regulations is the NHS number.

12. Subsection (3) sets out the conditions which must be met before the duty in subsection (4) applies. There are two conditions: (a) a 'relevant person' (i.e. a 'relevant health or adult social care commissioner or provider' as defined in new section 251C(2) of the HSCA 2012, inserted by clause 4) processes information about that individual; and (b) a consistent identifier of the description specified under subsection (1) relates to a particular individual. An effect of condition (b) is that if a description of consistent identifier, for example the NHS number, has been specified in regulations but there is

no such identifier in respect of a particular individual, for example that individual does not have a NHS number, then the duty in subsection (4) will not apply.

13. Subsection (4) sets out the new duty in respect of a consistent identifier specified in regulations. The duty is imposed on the relevant person, who must include the consistent identifier when processing the information. The duty applies whether the processing is internal record keeping, disclosure to another relevant health or social care commissioner or provider, or anything else recognised as 'processing' under the Data Protection Act 1998 ('DPA').

14. Subsections (5) to (8) set out qualifications to the duty in subsection (4) above.

15. Subsection (5) provides that the duty only applies so far as the relevant person considers that the inclusion is (a) likely to facilitate the provision to the individual of health services or adult social care in England, and (b) in the individual's best interests. New section 251C(5) expands upon the provision in (a).

16. Subsection (6) provides for certain criteria which, if any apply, mean the relevant person need not comply with the new duty. The criteria are: (a) the relevant person does not know the consistent identifier and is not reasonably able to learn it; (b) the individual objects, or would be likely to object, to the inclusion of the consistent identifier in the information; (c) the information concerns, or is connected with, the provision of health services or adult social care by an 'anonymous access provider' (as defined in new section 251C(6)); (d) for any other reason the relevant person is not reasonably able, or should not be required, to comply with the new duty. The effect of criterion (a) is that where the relevant person does not know the individual's consistent identifier (as specified in regulations) and has taken reasonable steps to find it out, such that the relevant person is not reasonably able to learn it, then the duty will not apply. Criterion (c) , interpreted in light of section 251C(6), will apply where the individual is receiving health or adult social care services anonymously, whether from the 'relevant person' or another commissioner or provider, for example services relating to sexual health or any other sensitive services. The effect of criterion (d) is that if, for any other reason, the relevant person is not reasonably able, or should not be required, to comply with the duty, then the duty will not apply. Other reasons may include where the cost of compliance for the relevant person would be too burdensome or disproportionately high. For example, some small or voluntary

organisations may not have the capacity or infrastructure to comply with this duty, in which case they should not be required to comply with it.

17. Subsection (7) means that the relevant person must still comply with any applicable provisions of the DPA and with any common law duty of care or confidence, and that this section does not permit doing anything inconsistent with the DPA or those common law duties.

18. Subsection (8) means that if the relevant person would be required to do anything under subsection (4) which they are already required to do under a contract by virtue of any provision of the National Health Service Act 2006, then the requirement under subsection (4) does not arise. This is for clarity and certainty as to the legal basis of certain obligations and to avoid any unnecessary duplication of obligations. For example, paragraph 74B of Schedule 6 to the National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291), as amended by the National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) Amendment Regulations 2014 (S.I. 2014/ 465), inserts contractual terms which require general practitioners to use NHS numbers in clinical correspondence relating to patients. The effect of subsection (8) is that the requirement on GPs to use the NHS number in clinical correspondences arises out of their contracts, not the new duty in subsection (4). Any enforcement would therefore be via their contracts.

Clause 3 – Duty to share information

19. This clause inserts new section 251B (duty to share information) into Part 9 of the HSCA 2012.

20. Subsection (1) of section 251B sets out the scope of the duty under subsection (2), namely that it applies in relation to information about an individual that is held by the 'relevant person' (that is, a 'relevant health or adult social care commissioner or provider' as defined in new section 251C(2)).

21. Subsection (2) imposes a duty on the relevant person to ensure that the information is disclosed to (a) persons working for the relevant person, and (b) any other relevant

health or adult social care commissioner or provider with whom the relevant person communicates about the individual.

22. Subsections (3) to (6) provide qualifications to the duty in subsection (2).

23. Subsection (3) provides that the duty only applies so far as the relevant person considers that the disclosure is (a) likely to facilitate the provision to the individual of health services or adult social care in England, and (b) in the individual's best interests. New section 251C(5) expands upon the provision in (a).

24. Subsection (4) provides for certain criteria which, if the relevant person reasonably considers one or more apply, mean the relevant person need not comply with the new duty. The criteria are: (a) the individual objects, or would be likely to object, to the disclosure of the information; (b) the information concerns, or is connected with, the provision of health services or adult social care by an 'anonymous access provider' (as defined in new section 251C(6)); (c) for any other reason the relevant person is not reasonably able, or should not be required, to comply with the new duty. Criterion (b), interpreted in light of section 251C(6), will apply where the individual is receiving health or adult social care services anonymously, whether from the 'relevant person' or another commissioner or provider, for example services relating to sexual health or any other sensitive services. The effect of criterion (c) is that if, for any other reason, the relevant person is not reasonably able, or should not be required, to comply with the duty, then the duty will not apply. Other reasons may include where the cost of compliance for the body would be too burdensome or disproportionately high. For example, some small or voluntary organisations may not have the capacity or infrastructure to comply with this duty, in which case they should not be required to do so.

25. Subsection (5) means that the relevant person must still comply with any applicable provisions of the DPA and any common law duty of care or confidence, and that this section does not permit doing anything inconsistent with the DPA or those common law duties.

26. Subsection (6) means that if the relevant person would be required to do anything under subsection (4) which is already required under a common law duty of care, then the requirement under subsection (4) does not arise. This is for clarity and certainty

as to the legal basis of certain obligations and to avoid any unnecessary duplication of obligations. Therefore, if disclosure of the information is already required under a common law duty of care then the effect of subsection (6) is that the legal basis of the requirement will arise from the common law duty of care, not the new duty in subsection (4). Any enforcement and remedies would therefore be in common law.

Clause 4 – Continuity of information: interpretation

27. This clause inserts into Part 9 of the HSCA 2012 new section 251C (continuity of information: interpretation), which makes provision for the interpretation of terms used in new sections 251A (consistent identifiers) and 251B (duty to share information).

28. Subsection (1) of section 251C provides that the section applies for the purposes of sections 251A to 251C.

29. Subsection (2) sets out the definition of 'relevant health or adult social care commissioner or provider' and thereby who the new duties are imposed on. The definition covers two categories of persons: (a) any public body so far as it exercises functions in connection with the provision of health services, or of adult social care in England; and (b) any person (other than a public body) so far as the person provides health services, or adult social care in England – (i) pursuant to arrangements made with a public body exercising functions in connection with the provision of such services, and (ii) otherwise than as a member or officer of a body or an employee of a person. Subject to regulations which may be made under subsection (3), if a person falls within either of those categories, then the person is subject to the new duties. The first category covers all public bodies which provide or commission health services or adult social care in England. The second category covers all private persons (in their capacity as contractors, not as employees or members or officers of a body) who have contracted with public body commissioners to provide health services or adult social care in England.

30. Subsection (3) confers on the Secretary of State a power to make regulations which provide for a person to be excluded, either generally or in particular cases, from the definition of 'relevant health or adult social care commissioner or provider'.

31. Subsection (4) clarifies that regulations made under subsection (3) may in particular provide for a person to be excluded in relation to the exercise of particular functions, or the exercise of functions in relation to particular descriptions of person, premises or institution.

32. Subsection (5) expands upon the reference in new sections 251A(5)(a) and 251B(3)(a) to a disclosure being likely to facilitate the provision of services or care to an individual. It provides that the disclosure will be treated as likely to facilitate the provision of services or care to the individual only if it does so directly, rather than by means of a clinical trial, a study or an audit or any other indirect means. This makes clear that the condition in new sections 251A(5)(a) and 251B(3)(a) limits the duties to use the consistent identifier and share information to the cases involving the direct care and treatment of an individual, and that they do not apply for any wider purpose. The duties would not, for example, require that the individual's data be shared for the purposes of research for the benefit of all individuals in a particular category or group, even though the individual may benefit from research into particular types of treatment.

33. Subsection (6) defines an 'anonymous access provider' for the purposes of new sections 251A(6)(c) and 251B(4)(b) in relation to services or care which are, or may be, received by individuals anonymously. The definition applies both in relation to services or care provided by the relevant provider or commissioner concerned and in relation to services or care provided to the individual by another commissioner or provider, such as a specialist to whom the provider or commissioner concerned refers the individual.

34. Subsection (7) provides that other terms used in new sections 251A to 251C have the same meaning as in section 250 HSCA 2012, subsection (7) of which provides definitions for the following terms: 'adult social care'; 'health services'; 'processing'; and 'public body'.

Clause 5 – Objectives in relation to the regulation of health and social care professions

35. This clause relates to the regulation of health and social care professionals.

36. *Subsection (1)* amends section 25 of the National Health Service Reform and Health Care Professions Act 2002 ('2002 Act'). It substitutes a new overarching objective for the existing objective of the Professional Standards Authority for Health and Social Care ('PSA'). The new objective applies only when the PSA is carrying out the functions set out in section 25(2)(b) to (d) of the 2002 Act, which are broadly:

    a) to promote best practice by regulators of health and care professionals in the performance of their functions;
    b) to formulate principles of good professional self-regulation and encourage health and care professional regulators to conform to them;
    c) to promote co-operation between health and care professional regulators and between them and other bodies that exercise corresponding functions.

37. This new objective, like the existing objective, does not apply to the functions of the PSA under section 25(2)(a) of the 2002 Act, to promote the interests of users of health care, social care in England, users of social work services in England and other members of the public in relation to the performance by the health and care professional regulators and any of their committees and officers of their functions.

38. The overarching objective is public protection, which involves the following:

    a) protecting, promoting and maintaining the health, safety and well-being of the public;
    b) promoting and maintaining public confidence in the professions that the regulators regulate;
    c) promoting and maintaining proper professional standards and conduct for members of those professions;
    d) promoting and maintaining proper standards in relation to the carrying on of retail pharmacy businesses at a registered pharmacy, and corporate bodies registered with the General Optical Council.

39. This clause also gives effect to the Schedule, which makes provision about the objectives of regulators of health and care professionals, and about when committees or panels of those regulators should have regard to those objectives.

The Schedule – Objectives of regulators of health and social care professions

40. This Schedule makes provision for a consistent overarching objective for the following regulators of health and social care professionals, by means of the following legislative amendments:

    a) the General Dental Council ('GDC') by amending section 1 of the Dentists Act 1984 to insert a new overarching objective;
    b) the General Optical Council ('GOC') by amending section 1 of the Opticians Act 1989 to replace the existing main objective with a new overarching objective;
    c) the General Osteopathic Council ('GOsC') by amending section 1 of the Osteopaths Act 1993 to insert a new overarching objective;
    d) the General Chiropractic Council ('GCC') by amending section 1 of the Chiropractors Act 1994 to insert a new overarching objective;
    e) the Nursing & Midwifery Council ('NMC') by amending Article 3 of the Nursing and Midwifery Order 2001 (S.I. 2002/253) to replace the existing main objective with a new overarching objective;
    f) the Health & Care Professions Council ('HCPC') by amending Article 3 of the Health and Social Work Professions Order 2001 (S.I. 2002/254) to replace the existing main objective with a new overarching objective;
    g) the General Pharmaceutical Council ('GPhC') by amending Article 6 of the Pharmacy Order 2010 (S.I. 2010/231) to replace the existing main objective with a new overarching objective.

41. Like the PSA's overarching objective, the overarching objective of the health and social care professional regulators involves the pursuit of the following objectives, which are essentially the same ones as apply in the case of the PSA:

    a) to protect, promote and maintain the health, safety and well-being of the public;
    b) to promote and maintain public confidence in the relevant profession;
    c) to promote and maintain proper professional standards and conduct for members of the relevant profession.

42. For the GOC and GPhC, which also have functions in relation to business regulation, the overarching objective also involves promoting and maintaining proper standards

and conduct for business registrants (GOC), and proper standards for the safe and effective practise of pharmacy at registered pharmacies (GPhC).

43. The Schedule also requires committees and panels to have regard to the overarching objective when determining if a practitioner is fit to practise or when considering appropriate sanctions. The committees and panels concerned are:

a) for the GDC, investigating committees when considering whether to issue a warning or advice, or direct a warning to be entered in the register, under sections 27A(2) and (3) and 36O(2) and (3) of the Dentists Act 1984, and practice committees when exercising functions in relation to determining fitness to practise and restoration to the register under sections 33 and 36W of the Dentists Act 1984;
b) for the GOC, registration appeals committees exercising functions under section 13K of the Opticians Act 1989 in relation to restoration to the register, fitness to practise committees exercising functions under section 13F and 13H of the Opticians Act 1989, and investigation committees when deciding whether to give a warning under section 13D(7) of the Opticians Act 1989;
c) for the GOsC, professional conduct committees when exercising functions in relation to restoration to the register under section 8 of the Osteopaths Act 1993 or fitness to practise under section 22, and health committees when exercising functions in relation to fitness to practise under section 23 of the Osteopaths Act 1993;
d) for the GCC, professional conduct committees when exercising functions in relation to restoration to the register under section 8 of the Chiropractors Act 1994 or fitness to practise under section 22, and health committees when exercising functions in relation to fitness to practise under section 23 of the Chiropractors Act 1994;
e) for the NMC, the investigating committee in relation to the exercise of some of its functions under article 26 of the Nursing and Midwifery Order 2001 (S.I. 2002/253) in respect of allegations referred to it, and the conduct and competence committees and health committees in the exercise of their functions in relation to fitness to practise and restoration to the register under articles 27 to 30 and 33 of S.I. 2002/253;
f) for the HCPC, the investigating committee in relation to the exercise of some of its functions under article 26 of the Health and Social Work Professions Order 2001 (S.I. 2002/254) in respect of allegations referred to it, and the conduct and competence committees and health

committees in the exercise of their functions in relation to fitness to practise and restoration to the register under articles 27 to 30 and 33 of S.I. 2002/254;

g) for the GPhC, investigating committees when deciding whether to give a warning or advice under article 53 of the Pharmacy Order 2010 (S.I. 2010/231) and fitness to practise committees in the exercise of their functions under articles 54 and 57 of that Order in relation to fitness to practise and restoration to the register.

44. The Schedule does not make similar provision for the General Medical Council (GMC) as these changes will be implemented for the GMC through secondary legislation (the draft General Medical Council (Fitness to Practise etc.) and the Professional Standards Authority for Health and Social Care (Referrals to Court) Order 2014). It also does not make similar provision for the Pharmaceutical Society for Northern Ireland, whose remit is different from that of the other regulators.

FINANCIAL EFFECTS

45. The continuity of information measures in the Bill will result in implementation costs for commissioners and providers of publicly funded health and adult social care. The Department of Health has estimated a total transition (that is, one-off) cost of £11.22m, with estimated annual benefits accruing in the form of savings of £1.2m through more efficient processing of information. Over the appraisal period of 10 years, the net present value is -£0.89m (that is, a net cost). However, the benefits estimated are thought to be a small proportion of the total potential benefits, and are anticipated to continue to accrue beyond the 10 year appraisal period.

PUBLIC SECTOR MANPOWER IMPLICATIONS

46. The Bill will not require a change to public sector manpower.

IMPACT ASSESSMENT

47. The impact on business of clause 1 will be through regulations under section 20 of the Health and Social Care Act 2008, which will not be changed as a result of this clause,

as regulations have already been made under that section that satisfy the new duty. An impact assessment for this has been produced.

48. However, the new duties in clauses 2 and 3 affect private businesses providing NHS-funded care or publicly funded adult social care. An impact assessment has been prepared which estimates a total one-off transition cost of £11.22m, and annual benefits of £1.2m, leading to a total net present value of -£0.89m (that is, a net cost). However, the benefits estimated are thought to be a small proportion of the total potential benefits, and are anticipated to continue to accrue beyond the 10 year appraisal period. The impact assessment also demonstrates a small positive impact to business, with a net present value over ten years of £1.61m. A small and micro business assessment was prepared as part of the impact assessment, which found an impact on small or micro businesses, and which set out actions to mitigate the risk of disproportionate burdens falling on such businesses.

49. An impact assessment is not required for clause 5 and the Schedule, since they are not a regulatory (or deregulatory) measure for business.

50. The Impact Assessment accompanying this Bill can be found in hard copy in the Vote Office.

COMPATIBILITY WITH THE EUROPEAN CONVENTION ON HUMAN RIGHTS (‘ECHR’)

51. This is a Private Member’s Bill and the Minister is not required to give a statement of compatibility with the Human Rights Act 1998 in accordance with section 19(1)(a) of that Act.

52. The Department of Health has, nevertheless, considered the question of compatibility and has concluded that the Bill is compatible with the European Convention on Human Rights.

COMMENCEMENT

53. All the Bill’s provisions other than clause 6 (extent, commencement and short title) are to be commenced by regulations by the Secretary of State.

54. The Government envisages that the regulations will provide for clauses 2 to 4 to be commenced on a common commencement date since they have an impact on

business, and for clause 5 and the Schedule to be commenced as agreed in discussions with the PSA and the professional regulators concerned.